REMARKS

Reconsideration and withdrawal of the rejections to this application are respectfully requested in view of the amendments and remarks made herewith, which place the application into condition for allowance.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1 and 3-10 are pending in this application. Claim 1 is currently amended, without prejudice. No new matter has been introduced by these amendments. Support for the amended recitations can be found throughout the specification.

It is submitted that these claims are patentably distinct from the prior art, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§§§101, 102, 103 or 112; but rather the remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. Rejections under 35 U.S.C. §103(a)

Claims 1 and 3-10 were rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over Hoffmann et al (U.S. Patent No. 5,538,736). Hoffmann allegedly teaches an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties, wherein the active substance-containing plaster can also contain further additives, such as plasticizers. The active-substance containing plaster taught by Hoffman contains a back side, a skin side with a back layer, an active substance reservoir which can contain one or more active substances, a contact adhesive device on the skin side and optionally a detachable cover layer, wherein the part of the active substance reservoir that remains on the skin has better adhesion to the skin than the back layer.

Hoffmann also allegedly teaches that apart from the basic materials, the plaster can also contain further suitable additives, including plasticizers. The Examiner contends that it would have obvious to one of ordinary skill in the art at the time the invention was made to include various suitable additives, particularly plasticizers, because they allegedly would serve to affect

the bonding or flow properties of adhesion. This rejection is respectfully traversed in view of the amendments to the claims and remarks made herewith.

The Examiner is respectfully reminded that establishing a *prima facie* case of obviousness requires that first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference must teach or suggest all the claim limitations. MPEP §2143.

Hoffmann relates to an active-substance containing plaster for controlled administration of active substances to the skin. The plaster described by Hoffmann has two active substance reservoirs, one of which can be detached. The problem to be solved and which Hoffmann addresses is a plaster characterized in that at least part of the active substance reservoir can be detached, while leaving one or more parts of said reservoir on the skin and the part of the active substance reservoir left behind on the skin has better adhesion to the skin than to the back layer (see Hoffmann, col. 2, lines 59-64). Therefore, the Hoffmann plaster comprises two types of adhesives: one that allows the plaster to be affixed to the skin, while the other type of adhesive allows one drug reservoir to be detached but retains a strong adhesion to the back layer of the plaster.

The instant invention relates to a plaster having reduced cold flow properties, wherein a core of adhesive is made flowable by addition of a plasticizer component. Additionally, the plaster comprises a ring of adhesive free of plasticizer. The ring of adhesive has a reduced flowability and stronger cohesion to skin, thereby reducing the appearance of a "dirty fringe" and decreasing adhesion to the packaging material. Therefore, the two types of adhesives described in the instant invention both promote cohesion to the skin, whereas the Hoffmann plaster requires that at least one region of adhesive is detachable from the skin, but retains strong adhesion to the back layer of the plaster.

Further, Hoffmann does not teach or suggest the advantage of spatially separating the two types of adhesives by addition of plasticizing agent. In fact, Hoffmann does not teach or suggest that the presence and absence of a plasticizing agent in an adhesive of the same patch could be used to improve the adhesive properties of the patch, with the purpose of preventing the appearance of a "dirty fringe" or to modulate the flow properties of the adhesive. Hoffmann is

silent regarding the change in adhesive properties afforded by addition of such a plasticizing component. One of ordinary skill in the art, seeking improved plasters comprising adhesives with stronger cohesion to skin and reduced cold flow properties that are spatially separated by the presence or absence of a plasticizer, would not look to the provisions of Hoffmann, because Hoffmann describes a plaster that has at least one active substance reservoir that comprises an adhesive that is detachably removed from the skin.

Hoffmann does not teach or suggest that adhesives exhibit cold flow properties. Notably, the drug reservoirs described by Hoffmann are not surrounded by a common adhesive ring, nor do individual adhesive rings surround each of the first and second drug reservoirs. Applicants do not believe that the Hoffmann plaster can be modified to arrive at the instant invention, wherein both first and second drug reservoirs are both together and/or separately surrounded by rings of adhesive to avoid cold flux.

Therefore, it is respectfully submitted that Hoffmann cannot be relied upon as prior art, because Hoffmann fails to teach or suggest every claim limitation. Furthermore, there is no suggestion, teaching, motivation, or incentive in Hoffmann to produce a transdermal patch with reduced cold flow properties comprising an area of adhesive containing plasticizer and an area of adhesive lacking plasticizer that both promote cohesion to the skin. The provisions of Hoffmann direct the skilled artisan to produce a multi-reservoir patch that has regions of adhesive that are detachably removed. Therefore, one of skill in the art could not have any reasonable expectation of success based on the teachings of Hoffmann.

Consequently, reconsideration and withdrawal of the §103(a) rejections in view of Hoffmann are respectfully requested.

Claims 1 and 3-10 were rejected under 35 U.S.C. §103(a) for allegedly being unpatentable in view of Mori (U.S. Patent No. 5,695,779). Mori allegedly teaches patch-type preparations comprising distinct adhesive layers, whereby microcapsules encapsulating drugs are contained in one area of the adhesive and are not contained or are excluded from the other adhesive area. The Examiner alleges that although Mori does not explicitly teach that the adhesive is 'made flowable' by a plasticizing additive, the recitation of "made flowable" was deemed to be a future-intended use limitation and therefore does not afford any patentable weight. Therefore, the Examiner contends that it would have been obvious to the skilled artisan to make a patch comprising similar components, used in the same field of endeavor and to treat

the same problems, in view of Mori. This rejection is respectfully traversed in view of the amendments to the claims and remarks made herewith.

Mori relates to a release-controlled transdermal therapeutic system comprising a rubber adhesive, microcapsules of drug, and a water-insoluble, rubber- and rubber solvent-insoluble, water absorbing resin powder. The rubbery adhesive used in the Mori transdermal system comprises a rubber adhesive component, a tackifier component, and a plasticizer component. Mori does not teach or suggest a patch with reduced cold flow properties.

The instant invention, on the other hand, relates to a patch with reduced cold flow properties, comprising an adhesive that comprises a plasticizer additive that imparts flowability, and a ring of adhesive that does not comprise a plasticizer and which imparts reduced flowability and stronger cohesion to skin. Therefore, the presently claimed invention describes a patch with two types of adhesives: one that contains plasticizer, and another type that lacks plasticizer.

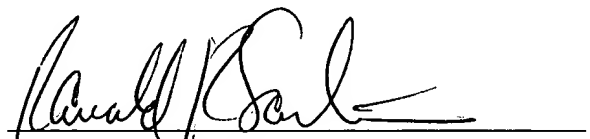
Respectfully submitted, Mori fails to render the present invention obvious, because Mori does not teach or suggest all of the claim limitations. Mori does not describe regions of the patch that comprise regions of adhesives that are spatially separate by addition of a plasticizing component. The provisions of Mori therefore provide no guidance to the skilled artisan regarding any advantage afforded by a region of adhesive lacking plasticizer surrounding a core of adhesive that contains plasticizer. In fact, Mori teaches away from the present invention by describing a transdermal system that comprises a plasticizer dispersed throughout the adhesive, and not confined to specific regions of the patch.

Therefore, the skilled artisan, seeking a patch with improved adhesive properties that reduces the appearance of a "dirty fringe", would not rely on the provisions of Mori, because Mori fails to describe a patch comprising spatially separate regions of adhesive. Furthermore, the transdermal system described by Mori comprises additional ingredients, such as microcapsules and a water-insoluble rubber- and rubber solvent-insoluble water-absorbing resin, which can change the adhesive properties of the system (see Mori, col. 2, lines 29-37). Based on the foregoing, an obviousness rejection cannot stand, and reconsideration and withdrawal of the §103(a) rejections under Mori are respectfully requested.

CONCLUSION

In view of the foregoing amendments, it is believed that the claims in this application are patentable, and early and favorable consideration thereof is earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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